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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Moses V. Chao

CHAO=11A

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/021,571	Applicant(s) CHAO ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2008 has been entered.

Response to Amendment

2. Claim 1 has been amended and claims 4 and 6 have been cancelled as requested in the amendment filed on July 03, 2008. Following the amendment, claims 1-3 are pending in the instant application.

Claims 1-3 are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on July 03, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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6. Claims 1-3 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record fully explained in section 5 of Paper mailed on May 11, 2007 and section 5 of Paper mailed on February 19, 2008.

At pp. 4-5 of the Response, Applicant resubmits previously presented arguments to support the asserted utility of the claimed polypeptides as markers for neuronal growth cones. Specifically, Applicant argues that the ARMS polypeptide “is localized specifically to growth cones and the synaptic region of neurons and nowhere else. The claimed polypeptide is not a general tissue marker which is merely expressed in a tissue- specific manner in neurons but rather is one of only three known polypeptides, from among the large number of tissue- specific polypeptides expressed in neurons, which can be used to specifically visualize only a particular region of neurons, the growth cones, as supported in the present specification at page 27”. Applicant further refers to the Declaration filed by Moses Chao, which provides additional explanations as why the utility of ARMS polypeptide as a growth cones marker is specific and substantial as asserted. Applicant’s arguments have been given careful consideration but are not persuasive for the following reasons.

At p. 27, the instant specification states, “as demonstrated in Example 2, the polypeptide of the present invention is a marker for growth cones as ARMS was found to be localized discretely at growth cones and in the synaptic regions of neurons. It was also found that ARMS co-localized with Vamp- 2, a synaptic vesicle marker, and can therefore be used for the same purposes as Vamp-2”. It is noted that the cited text does not provide for exclusive localization of ARMS polypeptide “to growth cones and the synaptic region of neurons and nowhere else”

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(emphasis added), as argued by Applicant. On the contrary, the specification specifically describes ARMS polypeptide as a ubiquitously expressed protein, “a polypeptide which is a transmembrane protein that is highly expressed in vertebrate central and peripheral nervous systems”([0009] at p. 5). Figures 5A-5D show the distribution of ARMS in rat CNS (pp. 7-8), DRG (Fig. 6A-6B), and in various brain regions (Fig. 7A-7C, pp. 8-9). The text at pp. 52-53 describes colocalization of ARMS with neurotrophin and ephrin receptors, which are not limited to growth cones only. Thus, the evidence of record does not support Applicant's statement of the specific and unique localization of ARMS to neuronal growth cones “and nowhere else”.

The Declaration of Moses V. Chao under 37 CFR 1.132 filed July 03, 2008 is insufficient to overcome the rejection of claims 1-3 based upon 35 U.S.C. 101 for the following reasons.

The Declaration makes a statement that ARMS is one of only three polypeptides known to be growth-cone specific: “ARMS polypeptide is localized discretely (and specifically) at growth cones and in the synaptic regions of neurons so as to serve as a marker for visualizing the growth cone of neurons (see page 27 of the present specification), which is particularly important when neuroscientists need to determine whether or not neurons are alive and making contacts and synapses, such as after neuronal injury. [...] Accordingly, the presently claimed ARMS polypeptide is specific for growth cones and is not a general tissue marker for neurons where any protein expressed in neuronal cells could be used for the same purpose.

After conducting an extensive search of the literature and of commercially available tissue markers/antibodies, I have found only two other proteins, VAMP-2 and GAP-43, besides ARMS, that are growth cone- specific.”

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The declaratory point has been fully considered but is not persuasive because, first, as fully explained earlier in the instant office action, the evidence of record contradicts Applicant's assertion that ARMS polypeptides are localized exclusively to the growth cones and absent in any other part of the neuronal body. Second, the art at the time of invention discloses a variety of polypeptides, which are suitable markers for neuronal growth cones. For example, articles of Katz et al., 1995 (J. Neuroscience, Vol. 5, No. 6, pp. 1402-11) and Van Vector et al., 1993 (Cell, Vol. 73, pp. 1137-53) identify several markers for neuronal growth cones (p46 protein and 1D4 antibody specifically). Further, article by Henry et al., 1999 (Cell Tissue Res., Vol. 297, pp. 67-79) discloses glycoprotein 93 (gp93) as localized on membranes of growth cones (see abstract); L1 and KIF4 are proteins highly concentrated in growth cones (see abstract of Peretti et al., 2000, J. Cell Biology, Vol. 149, pp. 141-52); CD151, CD81, CD63 and $\alpha 3 \beta 1$ integrin localize to growth cones (Stipp et al., 2000, J. Cell Science, Vol. 113, pp. 1871-82); Lutjens et al., 2000 article (Eur. J. Neurosci., Vol. 12, pp. 2224-34) names SCG10 as a membrane-associated protein of neuronal growth cones; finally, article of Berton et al., 2000 (Eur. J. Neurosci., Vol. 12, pp. 1294-1302) describes plurality of different proteins, which are exclusively or differentially expressed within neuronal growth cones. Thus, at the time of filing, synaptic region including pre-synaptic terminal, growth cones, synaptic vesicles and secretory granules have been extensively studied, described and markers for different parts of the synaptic junction and its organelles have been identified. Therefore, the utility of the instant novel naturally occurring protein as a marker for growth cones is neither specific nor substantial. It is not specific because nothing about this protein sets apart this particular marker of growth cones from any other polypeptide found in the neuronal growth cone. It is also not substantial because it is merely a

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hypothetical possibility of future uses, but not one for which the claimed polypeptides have been used in the real world (marking exclusively growth cones to the exclusion of other parts of neuronal body, “to determine whether or not neurons are alive and making contacts and synapses, such as after neuronal injury”, p. 2 of the Chao’s Declaration).

Thus, because nothing about Applicant’s asserted utility of ARMS protein as a tissue marker sets the claimed polypeptides apart from any other polypeptide located within growth cones (or rather from any other protein ubiquitously expressed in nervous system), Applicant has only disclosed general uses for ARMS proteins and not specific ones that satisfy U.S.C § 101, and the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

9. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649